<May 20, 2015>

Department of Health and Human Services
Division of Dockets Management, Food and Drug Administration
5630 Fishers Lane
Room 1061
(HFA – 305)
Rockville, Maryland 20852

Re: FDA Draft Guidance for Industry; <Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act> (Docket No. FDA-<2014-D-2138-0002>)

Dear Sir or Madam,

Baxter International Inc. ("Baxter") is pleased to have this opportunity to submit comments to Docket No. FDA-<2014-D-2138-0002>, *Draft Guidance for Industry; <Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act>* Baxter International Inc., through its subsidiaries and approximately <61,500> employees, develops, manufactures and markets products that save and sustain the lives of people with <hemophilia, immune disorders,> infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

We appreciate the opportunity to comment on this draft guidance and provide these recommendations for your consideration. The essence of the comments seeks to differentiate reporting from outsourcing facilities with an established pharmacovigilance system vs. those without. We respectfully submit the following comments:

Page/Section	Line Number	Proposed Change	Rationale
3/B Section 310.305	103-105	We propose adding a parenthetical statement as follows: "The regulations require reporting of each adverse drug experience received or otherwise obtained that is both serious and unexpected as soon as possible, but in no case later than 15 calendar days of initial receipt of the information along with a copy of the drug product's current labeling (for those products without an approved NDA)."	The cited regulation, 21 CFR 310.305, pertains to those products which do not have an approved NDA. Manufacturers currently are not required to submit a copy of the label with E2B reports for approved products. Therefore, we seek clarification that the sentence on lines 103-105 pertains only to products without an approved NDA (e.g., products compounded consistent with section 503B).
5/B Threshold	150-152	Baxter seeks additional discussion of the	This sentence describes

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Page/Section	Line Number	Proposed Change	Rationale
for Reporting		bolded sentence, "**Reports should be submitted as long as the outsourcing facility has information on at least the suspect drug and the adverse event.**"	adverse event reports which lack the four data elements required for adverse event reporting for approved drugs. We seek to understand the Agency's rationale for this guidance. FDA should consider clarifying that if a report lacks the four minimal data elements, the 503B outsourcing facility still should review the report for any potential safety issue.
6-7/ B Threshold for Reporting 3. Suspect Drug	219-223	We suggest adding a phrase (shown in bold) as follows: "If an adverse event involves multiple suspect drug products that are compounded by the same outsourcing facility, the outsourcing facility should submit only one report that notes the drug product considered most suspect by the reporter. If the reporter views each drug product as equally suspect, **or if the reporter does not identify a suspect drug**, the outsourcing facility should submit only one report that lists all of the drug products as suspect. In all cases, including those where not all of the drug products were made by the outsourcing facility, the report would include information on all suspect drug products."	The phrase "**or if the reporter does not identify a suspect drug**" is suggested for clarity.
7-8/C. How to Report Adverse Events	258-264	Baxter supports FDA's efforts to accept adverse events from outsourcing facilities through the E2B Gateway.	Baxter views an electronic reporting system as an important feature for timely notification of important safety information.

Thank you for the opportunity to provide comments to this notification. If you have questions, please do not hesitate to contact me at <224-270-4196> or <kathleen_o'neill@Baxter.com>

Respectfully submitted,

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